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Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-34

March 4, 1998

Gregory J. Hart
Administrative Director
Sarasota Community Blood Bank, Inc.
1760 Mound Street (US-41)
Sarasota, Florida 34236

Dear Mr. Hart:

During an inspection of your licensed blood bank from January 26 through February 5, 1998, our investigators, Joan S. Norton and Lourdes Valentin, documented violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), and the Current Good Manufacturing Practice (CGMP) regulations for blood and blood components [Title 21, Code of Federal Regulations, Part 606 (21 CFR 606)].

The inspection revealed that established written procedures for identifying unsuitable donors and donor deferral are not being followed. For example, your blood bank failed to place a donor who admitted to high risk behavior in permanent deferral, and when your blood bank learned that a donor may have had close contact with a person with hepatitis within the past year, you failed to place the donor in temporary deferral until your investigation into the donor's medical and social history was completed. The inspection also revealed that donor screening personnel failed to examine both arms of a donor for signs of narcotic addiction. However, the donor suitability record for the donor documented that the arms were found to be satisfactory.

During the inspection, our investigators observed an apheresis collection procedure that was discontinued due to a malfunction of the [redacted] apheresis machine and/or operator error. The contents of the apheresis machine bowl which contained 186 ml of donor blood and 100 ml of citrate phosphate anticoagulant were reinfused to the donor. The inspection revealed

that no written procedures have been established for reinfusing donor blood when an apheresis blood collection procedure is discontinued, nor have you established a criteria for determining whether the blood is suitable for reinfusion to ensure donor safety.

The inspection also revealed that your blood bank failed to follow established procedures in that [redacted] apheresis equipment operational qualifications were not performed prior to using the machines in the collection of red blood cells and plasma. For example, you received an [redacted] apheresis machine, serial # 94L163-1 on July 30, 1997, which was used for the collection of blood on August 5, 1997. However, your records show that this machine was not approved for use until January 20, 1998. Also, established written procedures for [redacted] apheresis equipment calibration, monthly maintenance, and cleaning to avoid possible cross contamination, are not being followed and there is no documentation available to show that personnel responsible for apheresis collections have completed their training and are deemed competent and qualified to operate the [redacted] apheresis equipment.

In addition, the inspection revealed that no written procedures are established for the current method and equipment employed in the manufacturing of cryoprecipitate AHF and there is no documentation available to show that personnel responsible for manufacturing cryoprecipitate AHF have been retrained after changes in manufacturing equipment and processing times.

We acknowledge receipt of your letter, dated February 18, 1998, submitted to this office in response to the Inspectional Observations (Form FDA 483) issued at the close of the inspection, addressing the observations and stating corrective actions taken. We consider this response to be inadequate in that examples of new or revised written procedures and other documentation (maintenance log, temperature log, and revised informed consent) to support your stated corrective actions were not provided for review. An example of a new comprehensive training plan for operating new plasma thawing equipment was not provided for review, and no time frames for completion of stated personnel retraining were specified. This response does not alleviate our concerns regarding the violations documented during the inspection.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood products produced and distributed by your blood bank are in compliance with the Act and the requirements of the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in administrative and/or regulatory action without further notice. Such action includes, license suspension and/or revocation, seizure and/or injunction.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct these violations, including examples of any documentation showing that corrections have been achieved. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Orlando, Florida 32751, telephone (407) 475-4731.

Sincerely,

Douglas D. Tolen
Director, Florida District